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United States Senate

WASHINGTON, DC 20510-2003

June 8, 2000

Ms. Melinda Plaisier
Associate Commissioner For Legislative Affairs
Food and Drug Administration
15-55 Parkland Building
5600 Fishers Lane
Rockville, Maryland 20857-0001

Dear Ms. Plaisier:

I am writing to request your consideration of the attached correspondence from Stephanie Gurwitz. Please respond directly to Ms. Gurwitz and send a copy to Mary Hanks of my staff. If you have any questions, please call Ms. Hanks at (202) 224-4654.

Thank you for your assistance.

Sincerely,

Barbara A. Mikulski

Barbara A. Mikulski
United States Senator

BAM:mh
Enclosure

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Stephanie J. Gurwitz
10393 Blue Arrow Ct. Columbia, MD 21044
410-730-9416 Email: zurgur@msn.com

Senator Barbara Mikulski
709 Hart Senate Office Building
Washington, DC 20510

March 3, 2000

Dear Senator Mikulski,

I am very concerned about a proposed FDA regulation implementing the PDMA. These regulations, which are scheduled to go into effect on December 3, 2000, would severely limit small and medium size businesses. The proposed changes decrease competition eliminating small wholesalers and giving unlimited control to manufacturers allowing them to determine who can distribute their product.

The regulations will cause a significant increase in the cost of pharmaceuticals, particularly those that are most heavily used by the elderly and critically ill.

If allowed to go into effect, the proposed changes will also impact retail pharmacies, veterinarians, and doctor's offices. No retail pharmacies would be able to provide a paper trail as required by the regulation to doctor's offices.

Repackaging companies that do not have direct contracts with manufactures will be cut out of the distribution system.

We need legislation to fix this problem *this year*. Unless a legislative change is likely to happen, businesses will start having to downsize this summer.

Practices have been in place guiding the pharmaceutical market for the past eleven years. No one, including FDA supporters of the regulation changes, have given concrete reasons why the changes are needed. There is no reason to change them now.

Thank you for your attention to this problem. I look forward to hearing the progress your office makes in this effort.

Sincerely,

Stephanie Gurwitz